

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent No.: 7,078,020)
Inventors: Joshua D. Rabinowitz et al.)
Issue Date: July 18, 2006)
For: DELIVERY OF ANTIPSYCHOTICS)
THROUGH AN INHALATION)
ROUTE)

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

REQUEST FOR CERTIFICATE OF CORRECTION

Pursuant to 35 U.S.C. § 255 and 37 C.F.R. § 1.323, this is a request for the issuance of a Certificate of Correction in the above-identified patent. Two (2) copies of PTO Form 1050 are appended. The complete Certificate of Correction involves one (1) page.

The mistake identified in the attached Form concerns the systematic (IUPAC) name for the drug loxapine which appears at column 12, lines 3-4 of the patent. The name reads:

2-chloro-11-(4-methyl-1-piperazinyl)-dibenz[b,f]-[1,4]diazepine

The name should read:

2-chloro-11-(4-methyl-1-piperazinyl)-dibenz[b,f]-[1,4]oxazepine.

The systematic name for loxapine is well-documented, *e.g.*, in scientifically accepted references such as The Merck Index. *See*, The Merck Index – An Encyclopedia of Chemicals, Drugs and Biologicals, 13th Ed., Maryadele J. O'Neil et al. (Eds.). Merck & Co., Inc. Whitehouse Station, NJ. 2001, p. 1001 (#5609) (attached).

The mistake identified in the attached Form is of a clerical or typographical nature, or of a minor character, and resulted from an error made in good faith by applicants. Therefore, Issuance of a Certificate of Correction correcting this error is requested.

The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to Deposit Account No. 19-5117.

Respectfully submitted,

Date: April 17, 2008

/Katherine Lobel-Rice/
Katherine Lobel-Rice, #58,079
Swanson & Bratschun, L.L.C.
8210 SouthPark Terrace
Littleton, Colorado 80120
Telephone: (303) 268-0066
Facsimile: (303) 268-0065

UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

Page 1 of 1

PATENT NO. : 7,078,020 B2

APPLICATION NO.: 10/750,303

ISSUE DATE : July 18, 2006

INVENTOR(S) : Joshua D. Rabinowitz et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 12, lines 3-4, "2-chloro-11-(4-methyl-1-piperazinyl)-dibenz[b,f]-[1,4]diazepine" should read
--2-chloro-11-(4-methyl-1-piperazinyl)-dibenz[b,f]-[1,4]oxazepine--.

MAILING ADDRESS OF SENDER (Please do not use customer number below):

Swanson & Bratschun, LLC
8210 SouthPark Terrace
Littleton, CO 80120

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

THE MERCK INDEX

AN ENCYCLOPEDIA OF
CHEMICALS, DRUGS, AND BIOLOGICALS

THIRTEENTH EDITION

Editorial Staff

Maryadele J. O'Neil, *Senior Editor*

Ann Smith, *Senior Associate Editor*

Patricia E. Heckelman, *Associate Editor*

John R. Obenchain Jr., *Editorial Assistant*

Jo Ann R. Gallepeau, *Technical Assistant*

Mary Ann D'Arecca, *Administrative Associate*

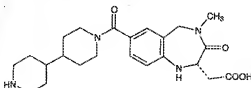
Susan Budavari, *Editor Emeritus*

*Published by
Merck Research Laboratories
Division of*

MERCK & CO., INC.
Whitehouse Station, NJ

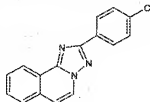
2001

228 (1998). Clinical evaluation in patients with coronary or cerebral atherosclerosis: R. A. Harrington *et al.*, *Circulation* 102 728 (2000).



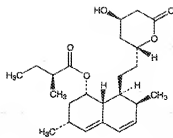
Zwitterionic. $[\alpha]_D^{20}$ -200.1° (c = 0.5 in methanol).
THERAP CAT: Antiplatelet.

5607. Lotifen. [66535-86-2] 2-(4-Chlorophenyl)-1,2,4-triazolo[5,1-a]quinoline; 2-(p-chlorophenyl)-s-triazolo[5,1-a]quinoline; L-12717; DL-717-IT; Canocenta; Privaprol. $C_{14}H_{10}ClN_4$; mol wt 279.73. C 68.70%, H 3.60%, Cl 12.67%, N 15.02%. Non-hormonal antifertility agent. Prepn: BE 815498. A. Omidi-Sale *et al.*, US 4075341 (1974, 1978 both to Lepetit). Pharmacokinetics: G. Galliani *et al.*, *J. Pharmacol. Dyn.* 5, 55 (1981). Pregnancy-terminating effect in dogs: G. Galliani, A. Omidi-Sale, *J. Small Anim. Pract.* 23, 295 (1982). Effect on subsequent fertility: G. Galliani *et al.*, *IRCS Med. Sci.* 12, 433, 435 (1984). Review: A. Assandri *et al.*, *Rev. Drug Metab. Drug Interact.* 4, 237 (1982).



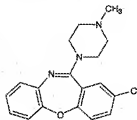
Crystals mp 238-240°.
THERAP CAT (VET): Abortifacient.

5608. Lovastatin. [75330-75-5] (2S)-2-Methylbutanoic acid (1S,3R,7S,8S,8aR)-1,2,3,7,8,8a-hexahydro-3,7-dimethyl-8-[2-[(2R,4R)-tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl]ethyl]-1-naphthalenyl ester; (1S,3R,7S,8S,8aR)-1,2,3,7,8,8a-hexahydro-3,7-dimethyl-8-[2-[(2R,4R)-tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl]ethyl]-1-naphthalenyl (5S)-2-methylbutyrate; 1,2,6,7,8,8a-hexahydro-β,8-dihydroxy-2,6-dimethyl-8-(2-methyl-1-oxobutoxy)-1-naphthaleneheptanoic acid 9-lactone; 2,6,6a-dimethyl-8a-(2-methyl-1-oxobutoxy)nevinic acid lactone; mevlinol; 6a-methylcompactin; monacolin K; MK-803; Lovastatin; Mevinacor; Mevinacor; Mevinor. $C_{24}H_{38}O_7$; mol wt 404.54. C 71.26%, H 9.97%, O 19.77%. Fungal metabolite; potent inhibitor of HMG-CoA reductase, the rate controlling enzyme in cholesterol biosynthesis. Isola from *Monascus ruber*: A. Endo, *J. Antibiot.* 32, 852 (1979); from *Aspergillus terreus*: R. L. Monaghan *et al.*, US 4231938 (1980 to Merck & Co.). Structure and biochemical properties: A. W. Alberts *et al.*, *Proc. Nat. Acad. Sci. USA* 77, 3957 (1980). Total synthesis: M. Hirama, M. Iwashita, *Tetrahedron Letters* 24, 1811 (1983). Review of syntheses: T. Rosen, C. H. Heathcock, *Tetrahedron* 42, 4909-4951 (1986). Biosynthesis: M. D. Green-span, J. B. Yudekovitz, *J. Bacteriol.* 162, 704 (1985); R. N. Moore *et al.*, *J. Am. Chem. Soc.* 107, 3694 (1985). HPLC determination in plasma and bile: R. J. Stubbs *et al.*, *J. Chromatogr.* 383, 438 (1986). Clinical pharmacology: S. M. Grundy, G. L. Vega, *J. Lipid Res.* 26, 1464 (1985). Clinical comparison with gemfibrozil, q.v.: M. J. Tikkanen *et al.*, *Am. J. Cardiol.* 62, 351 (1988). Review of clinical experience: J. A. Tobert, *Am. J. Cardiol.* 62, 283-341 (1988). Comprehensive description: G. S. Brenner *et al.*, *Anal. Profiles Drug Subs. Excerpt.* 21, 277-305 (1992). Prevention of acute coronary events in men and women with average cholesterol levels: J. R. Downs *et al.*, *J. Am. Med. Assoc.* 279, 1615 (1998).



White crystals, mp (under N_2): 174.5°. $[\alpha]_D^{25} +323^\circ$ (c = 0.5 g in 100 ml acetonitrile), uv max: 231, 247 nm ($A^{1\%}$ 1.02, 418). Soly at room temp (mg/ml): acetone 47, acetonitrile 28, n-butanol 7, i-butanol 14, chloroform 350, N,N-dimethylformamide 90, ethanol 16, methanol 28, n-octanol 2, n-propanol 11, i-propanol 20, water 0.4×10^{-3} . LD₅₀ orally in mice: >1000 mg/kg (Endo).
THERAP CAT: Antihyperlipoproteinemic.

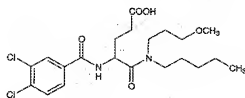
5609. Loxapine. [1977-10-2] 2-Chloro-11-(4-methyl-1-piperazinyl)dibenz[*b,f*]1,4-oxazepine; oxilapine; CL-62362; S-805; SUM-3170. $C_{21}H_{26}ClN_2O$; mol wt 327.82. C 65.95%, H 5.53%, Cl 10.81%, N 12.82%, O 4.88%. Prepn: NL 6406089 corresp to Schmutz *et al.*, US 3546226 (1964, 1970 both to Wander); *eidem* *Helv. Chim. Acta* 50, 245 (1967); Coppola, US 3412193 (1968 to Am. Cyanamid). Crystal structure: D. B. Cosulich, F. M. Lovell, *Acta Crystallogr.* 33B, 1147 (1977). Pharmacology: Schmutz *et al.*, *Chim. Ther.* 2, 424 (1967); Latimer, *J. Pharmacol. Exp. Ther.* 166, 151 (1969). Toxicity data: Stille *et al.*, *Arzneimittel-Forsch.* 15, 841 (1965). Toxicity studies: Mineshita *et al.*, *Oyo Yakuri* 4, 293 (1970), C.A. 76, 8145v (1972). Review of pharmacology and therapeutic efficacy: R. C. Heel *et al.*, *Drugs* 15, 198-217 (1978).



Pale yellowish crystals from petr ether, mp 109-110°. LD₅₀ orally in mice: 65 mg/kg (Stille).
Hydrochloride. Loxitane. $C_{21}H_{26}ClN_2O \cdot HCl$; mol wt 364.28.

Succinate. [27833-64-3] CL-71563; Loxapac; Loxitane. $C_{21}H_{26}ClN_2O \cdot C_4H_4O_4$; mol wt 445.90.
THERAP CAT: Anxiolytic.

5610. Loxiglumide. [107097-80-3] 4-[(3,4-Dichlorobenzoyl)amino]-5-[(3-methoxypropyl)pentylamino]-5-oxopentanoic acid; (±)-4-(3,4-dichlorobenzamido)-N-(3-methoxypropyl)-N-pentylglutaramic acid; CR-1505. $C_{24}H_{26}Cl_2N_2O_5$; mol wt 461.39. C 54.67%, H 4.65%, Cl 15.37%, N 6.07%, O 17.34%. Cholecystokinin A (CCK-A) antagonist. Prepn: F. Makovec *et al.*, WO 87 03689, *eidem*, US 4769389 (1987, 1988 both to Rotta). Pharmacology and receptor binding: I. Setaiker *et al.*, *Arzneimittel-Forsch.* 37, 703 (1987). Pharmacokinetics:



UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

Page 1 of 1

PATENT NO. : 7,078,020 B2

APPLICATION NO.: 10/750,303

ISSUE DATE : July 18, 2006

INVENTOR(S) : Joshua D. Rabinowitz et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 12, lines 3-4, "2-chloro-11-(4-methyl-1-piperazinyl)-dibenz[b,f]-[1,4]diazepine" should read
--2-chloro-11-(4-methyl-1-piperazinyl)-dibenz[b,f]-[1,4]oxazepine--.

MAILING ADDRESS OF SENDER (Please do not use customer number below):

Swanson & Bratschun, LLC
8210 SouthPark Terrace
Littleton, CO 80120

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.